

**--SEE OFFICE ACTION ON THE FOLLOWING PAGES--**

### Part III DETAILED ACTION

#### *Response to Amendment*

1. The Group and/or Art Unit location of your application in the PTO will change. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claim 126 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The method claim is not enabled because the specification does not provide an adequate written description, examples, or guidance for the following reasons. The antibodies used to perform the method are raised against antigens that are present in normal as well as cancerous prostate cells (Horszewicz, US 5,162,504, abstract and claim 1). Because the antigens are found in normal cells, the antibody would bind to normal cells, and the artisan would not have a predictable, reasonable expectation of success for using the instant invention to image prostate cancer because

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the composition of matter being used (the antibodies), cannot distinguish cancer cells from normal cells, i.e. the antibodies would bind to both normal and abnormal cells.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 119-126 are rejected under 35 U.S.C. 102(e) as anticipated by Horoszewics, Horoszewics discloses 7E11-C5, a monoclonal antibody that binds to PSMA (column 11, lines 27-56 and column 12, lines 31 to column 13, line 12) which meet all the limitations of the instant claims because of the inherency of SEQ ID NO:2 to PSMA. In addition, the open language of claim 121 and the recitation of the outside region is anticipated by Horoszewics.

7. Claims 119-122 are rejected under 35 U.S.C. 102(b) as anticipated by Feng et al.1991. Feng et al discloses of an isolated PSM antigen with a molecular weight of 100 kda and a monoclonal antibody which reacts with said antigen.

Applicant's arguments filed 6/17/99 have been fully considered but they are not persuasive. Applicant argues that the declarations of Kaladas, Rodwell, and Horoszewicz establish that the Feng reference is not enabling due to the lack of public availability of the 7E11-C5 hybridoma cell line. However, the 102(b) statute above clearly states that if the invention was described in a

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printed publication or in public use, the statute would apply. It is not required that the invention be described and be in public use. Regarding Applicant's arguments that the disclosure of the specific 7E11-C5 antibody should not anticipate a genus claim, since the Patent Office does not have the facilities for examining and comparing applicants' proteins with the proteins of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

*Applicant's arguments and declarations filed 3/2/00 have been fully considered but they are not persuasive because Applicant argues that 7E11-C5 and its antigen were not publicly available. However, the Examiner maintains the position that the instant invention was described in a printed publication which meets the statutory limitations.*

8. Claims 114-118 are in condition for allowance.

9. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0830 to 1700. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on

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(703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*SG*

Stephen Gucker

May 22, 2000

*Gary L. Kunz*  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200